DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 10, 2014

Folsom Metal Products, Inc. DBA Frontier Devices
Mr. Kevin Etheridge
Director of Engineering
153 A Cahaba Valley Parkway
Pelham, Alabama 35124

Re: K141106
Trade/Device Name: Frontier Devices FUSIO Screw Fuze System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fasteners
Regulatory Class: Class II
Product Code: OUR
Dated: May 30, 2014
Received: August 6, 2014

Dear Mr. Etheridge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141106

Device Name
Frontier Devices FUSIO Screw Fuze System

Indications for Use *(Describe)*
The FUSIO Screw Fuze System is intended for large bone fixation, including sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Section 5
510k Summary

The following information is provided as required by 21 CFR 807.87 for the 510(k) premarket notification for the bone screw system, Frontier Devices FUSIO Screw Fuze System.

Date Prepared:	October 07, 2014
Sponsor :	Frontier Devices 153A Cahaba Valley Parkway Pelham, AL 35124
FDA Registration #:	1065595
Contact Person:	Kevin Etheridge Director of Engineering 205-733-0901 (phone) 205-733-8445 (fax) kevin@frontierdevices.com
Proprietary Names:	Frontier Devices FUSIO Screw Fuze System
Common Names:	Bone screws
Classification Names: Regulatory Product Code	Smooth or threaded metallic bone fixation fasteners 888.3040 Class II OUR
Device Classification:	Class II
Predicate Devices:	Globus Medical SI –Lok Sacroiliac Joint Fixation System (K112028) Silex Sacroiliac Joint Fusion System (K123702)
Device Descriptions:	*Frontier Devices FUSIO Screw Fuze System* The Frontier Devices FUSIO Screw Fuze System consists of titanium bone screws of 7mm, 9.5mm, and 11mm diameter of various lengths to accommodate patient anatomy. An optional serrated washer can be placed on the screw. The screws are made from titanium alloy, Ti-6Al-4V, that conforms to the ASTM F136 standard.
Indications for Use:	The FUSIO Screw Fuze System is intended for large bone fixation, including sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Technology

The screws of the Frontier Devices FUSIO Screw Fuze System have characteristics, similar dimensions, designs and materials as the predicate devices. The screws are all made from titanium alloy (ASTM F136) with diameters and lengths which are similar to the predicate devices.

Performance Tests:

Performance tests on representative FUSIO Screw Fuze screws to have similar results as predicate screws. Tests measuring the insertion torque for representative screws of Frontier Devices FUSIO Screw Fuze System and predicate devices (Globus and X-Spine) into Grade 15 polyurethane foam blocks were conducted. The screws were inserted into the foam block and the peak torque was measured after 4 revolutions. The results were recorded and compared using mean torque values with standard deviations. The insertion torque measurements from the tests support the fact that the Frontier Devices FUSIO Screw Fuze System screws are substantially equivalent to predicate screws.

An engineering analysis was performed to show that the worst case Frontier Devices FUSIO Screw Fuze screw is substantially equivalent than the legally marketed X-Spine Silex screw predicate device. Using Solidworks, the screws were analyzed at the cross-section, more specifically at the middle of the screw, in order to determine if the screws would handle forces and associated stresses similarly. SolidWorks was also used to calculate the projected threaded area for forming a comparison of the projected thread engagement area for the FUSIO Screw Fuze screws and the predicate devices. In all areas studied, including overall sizes and materials, cross sectional mechanical properties, and thread properties, the FUSIO Screw Fuze results were substantially equivalent to those of the predicate device.

Cyclic bending tests were performed on the worst case FUSIO Screw Fuze screw design to verify the mechanical characteristics of the screw. Research was performed to determine the average forces and moments seen in the sacroiliac joint and to determine the number of “cycles” to use for testing. An endurance curve of the worst case screw was produced through mechanical testing, which yielded acceptable factors of safety for the force and moment. Based on the cyclic loading test results, the FUSIO Screw Fuze successfully passed the pass-fail criteria.

Substantial Equivalence:

The Frontier Devices FUSIO Screw Fuze System consists of screws that are similar in material composition and have the same indications for use as the predicate device. All of the technical characteristics are substantially equivalent to the corresponding characteristics of the predicate device. There may be slight differences in dimensions and shapes between the Frontier Devices FUSIO Screw Fuze System and the predicate device; however, these minor differences raise no new issues of safety and efficacy of the devices.